

May 12, 2004

PATENT APPLICATION  
DOCKET NO.: 3506.1002-003

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Steven B. Landau, Cheryl L. Miller and Matthew O. Fraser

Application No.: 10/817,332

Group Art Unit: Unknown

Filed: April 2, 2004

Examiner: Unknown

Confirmation No.: Unknown

Title: METHOD OF TREATING LOWER URINARY TRACT DISORDERS

CERTIFICATE OF MAILING OR TRANSMISSION

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INFORMATION DISCLOSURE STATEMENT

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Sir:

This Information Disclosure Statement is submitted:

☐ under 37 CFR 1.129(a), or

(First/Second submission after Final Rejection)

☒ under 37 CFR 1.97(b), or

(Within any one of the following time periods: three months of filing national application (other than a CPA) or date of entry of the national stage in an international application; or before the mailing date of a first office action on the merits in a non-provisional application, including a CPA, or a Request for Continued Examination).

☐ under 37 CFR 1.97(c) together with either:

☐ a Statement under 37 CFR 1.97(e), as checked below, or

☐ a \$180.00 fee under 37 CFR 1.17(p), or

(After the 37 CFR 1.97(b) time period, but before final action or notice of allowance, whichever occurs first)

☐ under 37 CFR 1.97(d) together with:

☐ a Statement under 37 CFR 1.97(e), as checked below, and

☐ a \$180.00 fee under 37 CFR 1.17(p), or

(Filed after final action or notice of allowance, whichever occurs first, but on or before payment of the issue fee)

☐ under 37 CFR 1.97(i):

Applicant requests that the IDS and cited reference(s) be placed in the application filewrapper.

(Filed after payment of issue fee)

Statement Under 37 CFR 1.97(e)

- ☐ Each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement; or
- ☐ No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

Statement Under 37 CFR 1.704(d) (Patent Term Adjustment)

Applies to original applications (other than design) filed on or after May 29, 2000

- ☐ Each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.
- ☒ Enclosed herewith is form PTO-1449:
  - ☒ Copies of the cited references are enclosed.
    - ☒ Since this application was filed after June 30, 2003, copies of issued U.S. patents and published U.S. applications are not required and are not being provided.
  - ☐ Copies of the cited references are enclosed except those entered in prior application, U.S. Application No. [ ], to which priority under 35 U.S.C. 120 is claimed. [The earlier application contains copies of the cited references.]
  - ☐ The listed references were cited in the enclosed International Search Report in a counterpart foreign application.
- ☒ The "concise explanation" requirement (non-English references) for reference AL2 under 37 CFR 1.98(a)(3) is satisfied by:
  - ☐ the explanation provided on the attached sheet.
  - ☐ the explanation provided in the Specification.
  - ☐ submission of the enclosed International Search Report.
  - ☐ submission of the enclosed English-language version of a foreign Search Report and/or foreign Office Action.
  - ☒ the enclosed English language abstract.

[X] Applicants request that the following non-published pending applications be considered:

Examiner's  
Initials

\_\_\_\_\_

U.S. Patent Application No. 10/757,364, by inventor Steven B. Landau, filed January 13, 2004, Docket No.: 3506.1000-002

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U.S. Patent Application No. 10/757,981, by inventors Steven B. Landau, Cheryl L. Miller and Karl B. Thor, filed January 13, 2004, Docket No.: 3506.1001-002

\_\_\_\_\_  
Examiner

\_\_\_\_\_  
Date

[X] A copy of each above-cited application, including the current claims, is enclosed.

[ ] A copy of each above-cited application, including the current claims, is enclosed, except those entered in prior application, U.S. Application No. [ ], to which priority under 35 U.S.C. 120 is claimed.

The Examiner is requested to return a copy of the above list of pending applications indicating which references were considered with the next office communication.

It is requested that the information disclosed herein be made of record in this application.

Method of payment:

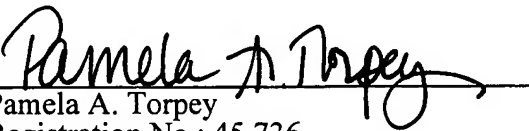
[ ] A check for the fee noted above is enclosed, or the fee has been included in the check with the accompanying Reply. A copy of this Statement is enclosed.

[ ] Please charge Deposit Account 08-0380 in the amount of \$[ ]. A copy of this Statement is enclosed.

[X] Please charge any deficiency in fees and credit any overpayment to Deposit Account 08-0380.

Respectfully submitted,

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Dated: *May 12, 2004*

PTO-1449 REPRODUCED

ATTORNEY DOCKET NO.  
3506.1002-003APPLICATION NO.  
10/817,332FIRST NAMED INVENTOR  
Steven B. LandauFILING DATE  
April 2, 2004EXAMINER  
UnknownCONFIRMATION NO.  
UnknownGROUP  
Unknown

## U.S. PATENT DOCUMENTS

EXAM- INER INI- TIAL	REF. NO.	DOCUMENT NUMBER Number-Kind Code (if known)	ISSUE DATE / PUBLICATION DATE MM-DD-YYYY	NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT
	AA	4,695,568	09-22-1987	Ninomiya, <i>et al.</i>
	AB	5,225,407	07-06-1993	Oakley, <i>et al.</i>
	AC	5,352,685	10-04-1994	Maruyama, <i>et al.</i>
	AD	5,663,343	09-02-1997	van der Meij, <i>et al.</i>
	AE	5,945,415	08-31-1999	Kato, <i>et al.</i>
	AF	5,962,494	10-05-1999	Young
	AG	5,977,127	11-02-1999	Bonnacker, <i>et al.</i>
	AH	6,300,336 B1	10-09-2001	Eeckhout, <i>et al.</i>
	AI	6,440,453 B1	08-27-2002	Fischer, <i>et al.</i>
	AJ	US 2002/0010216 A1	01-24-2002	Rogosky, <i>et al.</i>
	AK	US 2002/0107249 A1	08-08-2002	Wong, <i>et al.</i>
	AA2	US 2003/0158221 A1	08-21-2003	Zhang, <i>et al.</i>
	AB2	US 2003/0203055 A1	10-30-2003	Rao, <i>et al.</i>
	AC2	6,465,458 B1	10-15-2002	Wong, <i>et al.</i>
	AD2	6,355,647 B1	03-12-2002	Steiner, <i>et al.</i>
	AE2	4,939,136	07-03-1990	Haeck, <i>et al.</i>
	AF2	US 2001/0020025 A1	09-06-2001	Megens
	AG2	US 2002/0002197 A1	01-03-2002	Mueller, <i>et al.</i>
	AH2			
	AI2			
	AJ2			
	AK2			
	AA3			
	AB3			
	AC3			

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(Use several sheets if necessary)

## FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER Country Code-Number-Kind Code (if known)	DATE MM-DD-YYYY	NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT	TRANSLATION	
					YES	NO
	AL	WO 01/26623 A3	04-19-2001	Laxdale Limited		
	AM	WO 03/063873 A1	08-07-2003	Arachnova Therapeutics Ltd.		
	AN	WO 00/48581 A3	08-24-2000	Novartis AG		
	AO	WO 02/094249 A1	11-28-2002	Arachnova Therapeutics Ltd.		
	AP	WO 03/077897 A1	09-25-2003	Cypress Bioscience, Inc.		
	AQ	WO 2004/004734 A1	01-15-2004	Arachnova Therapeutics Ltd.		
	AL2	WO 98/50037	11-12-1998	Mitsubishi Chemical Corporation		X
	AM2	WO 03/061657 A1	07-31-2003	Aryx Therapeutics		
	AN2	WO 2004/019948 A1	03-11-2004	Arachnova Therapeutics Ltd.		
	AO2					
	AP2					
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	AL4					
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EXAMINER

DATE CONSIDERED

PTQ-1449 REPRODUCED  <b>INFORMATION DISCLOSURE CITATION IN AN APPLICATION</b>  <b>May 12, 2004</b>  (Use several sheets if necessary)	ATTORNEY DOCKET NO. 3506.1002-003		APPLICATION NO. 10/817,332	
	FIRST NAMED INVENTOR Steven B. Landau		FILING DATE April 2, 2004	
	EXAMINER Unknown	CONFIRMATION NO. Unknown	GROUP Unknown	

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
AR	Andersson, K.E., "Treatment of the Overactive Bladder: Possible Central Nervous System Drug Targets," <i>Urology</i> , 59 (Suppl 5A):18-24 (2002).	
AS	Andersson, K.E., "Bladder Activation: Afferent Mechanisms," <i>Urology</i> , 59 (Suppl 5A):43-50 (2002).	
AT	Morrison, J. <i>et al.</i> , "Neurophysiology and Neuropharmacology" In: Incontinence (vol. 2) Abrams, P., Cardozo, L., Khoury, S., and Wein, A., Eds. (UK, Health Publications, Ltd.,) pp. 83-163 (2002).	
AU	Owens, M. J. <i>et al.</i> , "Neurotransmitter Receptor and Transporter Binding Profile of Antidepressants and their Metabolites <sup>1</sup> ," <i>J. Pharmacol. Exp. Ther.</i> , 283(3): 1305-1322 (1997).	
AV	Sharma , A. <i>et al.</i> , "Pharmacokinetics and Safety of Duloxetine, a Dual-Serotonin and Norepinephrine Reuptake Inhibitor," <i>J. Clin. Pharmacol.</i> , 40:161-167 (2000).	
AW	Thor, K. B. <i>et al.</i> "Effects of Duloxetine, a Combined Serotonin and Norepinephrine Reuptake Inhibitor, on Central Neural Control of Lower Urinary Tract Function in the Chloralose-Anesthetized Female Cat," <i>J. Pharmacol. Exp. Ther.</i> , 274: 1014-1024 (1995).	
AX	Downie, J.W., "Pharmacological Manipulation of Central Micturition Circuitry," <i>Curr. Opin. CPNS Inves. Drugs</i> , 1(2):231-239 (1999).	
AY	Khan, M.A. <i>et al.</i> , "Doxazosin Modifies Serotonin-Mediated Rabbit Urinary Bladder Contraction. Potential Clinical Relevance," <i>Urol. Res.</i> , 28:116-121 (2000).	
AZ	Metts, J. F., "Interstitial Cystitis: Urgency and Frequency Syndrome," <i>American Family Physician</i> , 64(7): 1199-1206 (2001).	
AR2	Theoharides, T. C. and Sant, G.R., "New Agents for the Medical Treatment of Interstitial Cystitis," <i>Exp. Opin. Invest. Drugs</i> , 10(3): 521-546 (2001).	
AS2	Collins M.M. <i>et al.</i> , "How Common is Prostatitis? A National Survey of Physician Visits," <i>J. Urol.</i> , 159:1224-1228 (1998).	
AT2	Eguchi, J. <i>et al.</i> , "Pharmacological Profile of the Novel Antidepressant 4-(2-Fluorophenyl)-6-methyl-2-(1-piperazinyl)thieno-[2,3-d]pyrimidine Monohydrate Hydrochloride," <i>Arzneim.-Forschung/Drug Res.</i> , 47(12): 1337-47 (1997).	
AU2	Wood, J.D. <i>et al.</i> "Fundamentals of Neurogastroenterology," <i>Gut</i> , 45(Suppl II):II6-II16 (1999).	

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PTO-1449 REPRODUCED  <b>INFORMATION DISCLOSURE CITATION IN AN APPLICATION</b>  <b>May 12, 2004</b>  (Use several sheets if necessary)	ATTORNEY DOCKET NO. 3506.1002-003		APPLICATION NO. 10/817,332	
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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
AV2	Center for Drug Evaluation and Research Application Number: 020623; Pharmacology Reviews; July 5, 1996.	
AW2	Kilpatrick, G.J. <i>et al.</i> , "Identification and Distribution of 5-HT <sub>3</sub> Receptors in Rat Brain Using Radioligand Binding," <i>Nature</i> , 330: 746-748 (1987).	
AX2	Butler, A. <i>et al.</i> , "Pharmacological Properties of GR38032F, a Novel Antagonist at 5-HT <sub>3</sub> Receptors," <i>Br. J. Pharmacol.</i> , 94(2): 397-412 (1988).	
AY2	Ito, C. <i>et al.</i> , "Effect of GK-128 [2-[(2-Methylimidazol-1-yl)methyl]-benzo[f]thiochromen-1-one Monohydrochloride Hemihydrate], a Selective 5-Hydroxytryptamine <sub>3</sub> Receptor Antagonist, on Colonic Function in Rats," <i>J. Pharmacol. Exp. Ther.</i> , 280(1): 67-72 (1997).	
AZ2	Chuang, Y.C. <i>et al.</i> , "Intravesical Protamine Sulfate and Potassium Chloride as a Model for Bladder Hyperactivity," <i>Urology</i> , 61(3): 664-670 (2003).	
AR3	Sasaki, K. <i>et al.</i> , "Diabetic Cystopathy Correlates with a Long-Term Decrease in Nerve Growth Factor Levels in the Bladder and Lumbosacral Dorsal Root Ganglia," <i>J. Urol.</i> , 168(3): 1259-1264 (2002).	
AS3	Yoshimura, N. and Chancellor, M. B., "Current and Future Pharmacological Treatment for Overactive Bladder," <i>J. Urol.</i> , 168:1897-1913 (2002).	
AT3	Appell, R. A. <i>et al.</i> , "Prospective Randomized Controlled Trial of Extended-Release Oxybutynin Chloride and Tolterodine Tartrate in the Treatment of Overactive Bladder: Results of the OBJECT Study," <i>Mayo Clin. Proc.</i> 76:358-363 (2001).	
AU3	Elmiron® (pentosan polysulfate sodium), capsules, <i>Product Information</i> , Ortho-McNeil Pharmaceutical, Inc., Raritan, N.J. (2002).	
AV3	Elliott, D. S. <i>et al.</i> , "Medical Management of Overactive Bladder," <i>Mayo Clin. Proc.</i> 76:353-355 (2001).	
AW3	Tonini, M. <i>et al.</i> , "Characterization of the 5-HT Receptor Potentiating Neuromuscular Cholinergic Transmission in Strips of Human Isolated Detrusor Muscle," <i>Br. J. Pharmacol.</i> , 113(1):1-2 (1994).	
AX3	Espey, M.J. <i>et al.</i> , "Serotonergic Modulation of Spinal Ascending Activity and Sacral Reflex Activity Evoked by Pelvic Nerve Stimulation in Cats," <i>Brain Res.</i> , 798(1-2):101-108 (1998).	

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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
AY3	Yoshida, A. <i>et al.</i> , "5-Hydroxytryptamine Receptors, Especially the 5-HT <sub>4</sub> Receptor, in Guinea Pig Urinary Bladder," <i>Jpn. J. Pharmacol.</i> , 89(4):349-355 (2002).	
AZ3	Kodama, M. and Takimoto, Y., "Influence of 5-Hydroxytryptamine and the Effect of a New Serotonin Receptor Antagonist (Sarpogrelate) on Detrusor Smooth Muscle of Streptozotocin-Induced Diabetes Mellitus in the Rat," <i>International Journal of Urology</i> 7:231-235 (2000).	
AR4	Katofiasc, M. A. <i>et al.</i> , "Comparison of the Effects of Serotonin Selective, Norepinephrine Selective, and Dual Serotonin and Norepinephrine Reuptake Inhibitors on Lower Urinary Tract Function in Cats," <i>Life Sci.</i> , 71:1227-1236 (2002).	
AS4	Andersson, K. E., "Treatment of Overactive Bladder: Other Drug Mechanisms," <i>Urology</i> , 55(Supplement 5A):51-59 (2000).	
AT4	Testa, R. <i>et al.</i> , "Effect of Different 5-Hydroxytryptamine Receptor Subtype Antagonists on the Micturition Reflex in Rats," <i>BJU Int.</i> , 87(3):256-264 (2001).	
AU4	Barras, M. <i>et al.</i> , "Characterisation of the 5-HT Receptor Potentiating Neurotransmission in Rabbit Bladder," <i>Eur. J. Pharmacol.</i> , 318(2-3):425-428 (1996).	
AV4	Eguchi, J. <i>et al.</i> , "The Anxiolytic-like Effect of MCI-225, a Selective NA Reuptake Inhibitor with 5-HT <sub>3</sub> Receptor Antagonism," <i>Pharm., Biochem. and Behavior</i> 68:677-683 (2001).	
AW4	Burns, M. J., The Pharmacology and Toxicology of Reboxetine, [Retrieved from the Internet 2002-12-04]. Retrieved from the Internet < <a href="http://www.ijmt.net/3_4/3_4_26.html">http://www.ijmt.net/3_4/3_4_26.html</a> >.	
AX4	Bymaster, F. P. <i>et al.</i> , "Comparative Affinity of Duloxetine and Venlafaxine for Serotonin and Norepinephrine Transporters <i>in vitro</i> and <i>in vivo</i> , Human Serotonin Receptor Subtypes, and Other Neuronal Receptors," <i>Neuropharmacol.</i> , 25(6):871-880 (2001).	
AY4	Béïque, J.-C. <i>et al.</i> , "Affinities of Venlafaxine and Various Reuptake Inhibitors for the Serotonin and Norepinephrine Transporters," <i>Eur. J. Pharmacol.</i> , 349:129-132 (1998).	
AZ4	Wong, E. H. F. <i>et al.</i> , "Reboxetine: A Pharmacologically Potent, Selective, and Specific Norepinephrine Reuptake Inhibitor," <i>Biol. Psych.</i> , 47(9):818-829 (2000).	
AR5	Fairweather, D. B. <i>et al.</i> , "The Psychomotor and Cognitive Effects of Litoxetine in Young and Middle Aged Volunteers," <i>Br. J. Clin. Pharmacol.</i> 40:119-125 (1995).	

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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
AS5	LOTRONEX (alosetron hydrochloride) - Tablets, <i>Product Information</i> , GlaxoSmithKline, Research Triangle Park, NC, pp. 1-13 (2002).	
AT5	GB 0216027.3 filed 07-10-2002, entitled "New Therapeutic Use," priority document for WO 2004/004734 A1 (Reference AQ).	
AU5	GB 0220064.0 filed 08-29-2002, entitled "New Therapeutic Use," priority document for WO 2004/019948 A1 (Reference AN2).	
AV5	GB 0316115.5 filed 07-09-2003, entitled "New Therapeutic Use of 4-(2-Fluorophenyl)-6-Methyl-2-(1-Piperziny) Thieno[2,3-D] Pyrimidine," priority document for WO 2004/019948 A1 (Reference AN2).	
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AX5	U.S. Provisional Application No. 60/364,531 filed 03-15-2002, entitled "Methods of Treating Visceral Pain Syndromes," by Rao <i>et al.</i> , priority document for WO 03/077897 A1 (Reference AP) and U.S. 2003/0203055 A1 (Reference AB2).	
AY5	Chancellor, M.B., "New Frontiers in the Treatment of Overactive Bladder and Incontinence," <i>Reviews in Urology</i> , 4(4): S50-S56 (2002).	
AZ5	Evans, R.J., "Treatment Approaches for Interstitial Cystitis: Multimodality Therapy," <i>Reviews in Urology</i> , 4(Suppl. 1): S16-S20 (2002).	
AR6	Simon, H. <i>et al.</i> Eds., " Benign Prostatic Hyperplasia and Lower Urinary Tract Symptoms", [Retrieved from the Internet 2003-18-03]. Retrieved from the Internet < <a href="http://wellness.ucdavis.edu/medical_conditions_az/prostaticyperplasia71.html">http://wellness.ucdavis.edu/medical_conditions_az/prostaticyperplasia71.html</a> >.	

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